UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JAN 27 1981

ORDER AND NOTICE

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Dear Registrant:

In the August 29, 1980 ORDER AND NOTICE issued under Section (3)(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 136a (c)(2)(B), EPA informed registrants of 2,4-D products of a variety of data-submission requirements. This letter modifies some aspects of our original request for data and clarifies other requirements that may not have been fully understood by registrants. Except for changes made in this letter, the original ORDER AND NOTICE remains in effect.

First, the Agency is deferring the requirement for the studies on acute oral toxicity and acute dermal toxicity of end-use products containing 2,4-D. The Agency will group the 2,4-D end-use products and require testing on a representative sample for each group. This action will achieve a better balance between the Agency's need for more data on acute toxicity and the Agency's desire to avoid the unnecessary duplication of data. It will also relieve small manufacturers of the burden of producing data for each of the numerous end-use products.

In this way, the information needed can be generated by fewer studies. The lower cost of this reduced number of studies can be shared among the registrants. EPA will inform registrants of the revised requirements and the timetable for submission of data at a later date.

Registrants of manufacturing-use products are still required to submit acute oral and dermal toxicity studies for those products. The Agency has grouped these products (see Appendix I), and registrants may cooperate to produce one set of tests for each group. The terms of the August 29 ORDER AND NOTICE continue to apply to these acute studies. The schedule for submission of these studies is May 1, 1981. Registrants may request a time extension, if necessary, with an adequate rationale. The registrants of manufacturing-use products should refer to the August ORDER AND NOTICE for detailed guidance. Page 3 of the earlier ORDER AND NOTICE requires registrants to respond in one of six ways for each product.

These six options, with comments explaining why some of the options are not appropriate responses to this request for acute toxicity data, are:

(A) You must notify EPA that you are willing to produce and submit the data yourself;

(B) You must notify EPA that you have entered into an agreement, with one or more of the other registrants who are subject to this notice's requirements, to jointly produce and submit the data, or to share in the cost of this work;

(C) You must provide to EPA the "Statement of Willingness to Enter Into an Agreement with Other Registrants for Development of Data", in accordance with Section V and Appendix C of the August 29th ORDER AND NOTICE, which will allow EPA to exempt you, under certain circumstances, from the consequences of not submitting some or all of these data;

Options (B) and (C) apply to joint studies of a single test substance that serve to meet data submission requirements for two or more products. These options are appropriate for products which have been grouped together. Registrants may jointly produce the data for each group, or a registrant may choose to produce acute oral and dermal toxicity studies for his own product;

(D) This option applies only to end-use products;

(E) This option provides for waiver requests. The studies being requested on acute oral and dermal toxicity provide the minimum amount of information on such toxicity that is acceptable to the Agency. By thus reducing the scope of the request for such data, EPA thinks that it has eliminated the circumstances under which waiver requests can be justified. Accordingly, the Agency does not contemplate granting waivers of these minimum requirements for data production.

(F) You must file with EPA a request that the registration(s) for your products containing any or all forms of 2,4-D be voluntarily cancelled.

If a registrant has an existing study which may fill one of the requirements in this Notice, that study may be submitted to the Agency. We will promptly review the study to determine if it is scientifically valid and satisfies the requirement.

Registrants of manufacturing-use products have 30 days from receipt of this letter to respond to the requirement for acute oral and acute dermal toxicity tests on each manufacturing-use product. If your company has registered manufacturing-use products, a list of manufacturing-use products and registrants is attached to this notice. You may use this list to identify products for which joint data production is appropriate. (Appendix II). If affected registrants do not respond within 30 days, the Agency may suspend their registrations as stated in the earlier ORDER AND NOTICE.

Registrants are also reminded that dermal absorption studies on some liquid and emulsifiable concentrate end-use products will still be required, as mentioned in the August 29th ORDER AND NOTICE. EPA is developing a protocol for these studies, and consolidating these data requirements so that each end-use product need not be tested. As in the case of the acute oral and dermal toxicity data requirements, this action will substantially reduce the number of studies to be done, avoiding needless duplication of data and unnecessary hardship on small manufacturers. Registrants will be notified at a later date of the protocol to be followed, the revised data requirements, and the scheduled date for submission of the studies.

If you have any questions concerning this letter, or the orginial ORDER AND NOTICE, you may contact Patricia Cohn at (703) 557-7973 for further information.

Sincerely yours,

Edwin L. Johnson

Edwin L. Johnson
Deputy Assistant Administrator
for Pesticide Programs

APPENDIX I

Grouping of 2,4-D Manufacturing-Use Products for Acute Oral and Dermal Testing

The Agency will accept one set of acute oral and acute dermal toxicity tests for each group of products identified below. The basis for developing these groups is that the Agency anticipates one set of acute oral and dermal LD_{50} values will adequately represent all products in the group. The Agency may require additional actue toxicity tests within a group if a review of the single set of tests indicates that they may not be representative of all products in the group.

The products that the Agency will accept as the test substance for each group are indicated with an asterisk.* Any registrant may choose to test his own product rather than to participate in testing the representative product for the group.

Note: Products containing silvex are suspended, therefore no testing is required on these products at this time.

Acute oral and dermal toxicity studies are not being required on formulation interimediates in granular form.

2,4-Dichlorophenoxyacetic acid technical grade

Product numbers

1990 - 390*

264 - 247*

359 - 579*

464 - 453*
464 - 454*

524 - 3* - this registration is being transferred to registrant number 34704

677 - 266*

2217 - 455*

6305 - 11*

7501 - 23* - this registration is being transferred to registrant number 400

7969 - 22*

39335 - 3
39335 - 30

39511 - 60

In order to determine whether the following two technical grade 2,4-D acids may be grouped with the above products, the Agency must receive an accurate, current confidential statement of formula for these products within 15 days from receipt of this letter. The Agency will promptly review the Confidential Statements of formula and notify registrants whether they may participate in the above group or must produce separate acute toxicity tests. If the Agency does not receive the Confidential Statements of formula the registrants must produce separate acute oral and dermal toxicity tests for each of these two products.

2217-632

7969 -29

Sodium 2,4 Dichlorophenoxyacetate technical grade and formulation intermediate

228 - 123*

39335 - 26

Isooctyl 2,4 dichlorophenoxyacetate technical grade

1990 - 388*
228-126*
464-458*

The Agency has grouped all isooctyl esters of 2,4-D together for this testing. However, each registrant of product(s) within this group must submit a confidential statement of formula including the Chemical Abstracts nomenclature for all ingredients.

524 - 94* - this product is being transferred to registrant number 34704

677 - 251*
677 - 255*

39511 - 62*

40831 - 119*

359 - 577*

Butyl 2,4-dichlorophenoxyacetate technical grade

228 - 128*

464 - 456*

524 - 62* - this registration is being transferred to registrant number 34704

677 - 252*

39511 - 61*

Isobutyl 2,4-dichlorophenoxyace ate technical grade

1990 - 389*
359 - 584*

Butoxyethyl 2,4-dichlorophenoxy cetate technical grade

228 - 136*

464 - 518

39511 - 63*

Isopropyl 2, 4-dichlorophenoxya etate

677 - 249*

5481 - 144*

Formulation Intermediates - imethylamine

464 - 4578* - either of thes two products may be
677 - 246* tested

2217 - 488*
- 493
- 531
- 571
- 602
- 623
- 625

39335 - 27

2217 618 this product must be tested

Formulation Intermediates - iethonolamine

2217 - 524 this product must be tested

2217 - 491 this product must be tested

Formulation Intermediate - Butoxyethyl 2,4-D

228 - 141 this product must be tested